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CONFIRMATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE Q65986 8688 08/31/2001 Hideya Takeo 09/943,347 EXAMINER 7590 09/08/2004 SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC LAVIN, CHRISTOPHER L 2100 Pennsylvania Avenue, N.W. Washington, DC 20037-3202 PAPER NUMBER ART UNIT 2621

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/943,347	TAKEO, HIDEYA
	Examiner	Art Unit
	Christopher L Lavin	2621
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR-REPLY IS SET-TO-EXPIRE 3.MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1)⊠ Responsive to communication(s) filed on <u>31 August 2001</u> .		
) This action is FINAL . 2b) This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1 - 11 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1 - 3, 5, 6, 8, 9, and 11 is/are rejected. 7) Claim(s) 4,7 and 10 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 31 August 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Di 5) Notice of Informal F 6) Other:	ate Patent Application (PTO-152)

Application/Control Number: 09/943,347

Art Unit: 2621

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to because in Fig. 2 step B1 should read "SQUARE AREA EXTRACTED". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Application/Control Number: 09/943,347 Page 3

Art Unit: 2621

Specification

3. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

- 4. Throughout the specification there are numerous grammatical errors, which while not precluding comprehension of the claims hinder understanding of the concepts. Several examples of these grammatical errors can be seen in the first paragraph of the background art. The sentence starting out on line 19 is a perfect example of unclear language; it is barely understandable in its current state.
- 5. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1 3, 6, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke (5,799,100).
- 8. In regards to claim 1, Clarke discloses the system of claim 1 in Fig. 1 with further detail elaborated upon throughout this rejection. The paragraph starting at column 4, line 27 discloses a system for image enhancement and analysis of abnormal regions.

Page 4

Application/Control Number: 09/943,347

Art Unit: 2621

Portion 5 of Fig. 1 discloses the step of classifying an image region as either normal tissue or an abnormal shadow. Portion 7 of Fig. 1 discloses a computer monitor display used to output information on the prospective abnormal shadows detected by the system. Portion 6 of Fig. 1 discloses the step of classifying an abnormal shadow as either benign or malignant. The paragraph starting at column 5, line 12 discloses that segmented images are output to the monitor system that displays the abnormal shadow region. Inherent with outputting regions of interest and determining whether a shadow is malignant or benign is providing some means to alert the user through the display system what kind of mass has been discovered.

- 9. In regards to claim 2, Clarke discloses in portion 6 of Fig. 1 the step of computing the probability that an abnormal shadow is malignant. This is further discussed in the paragraph staring on column 16, line 9. The probability acts as an index of malignancy. The only reason to compute such information would be to share it with the user through the display system.
- 10. In regards to claims 3, 6, and 9, Clarke discloses portion 5 of Fig. 1 the step of classifying tissue as either mass or normal, this creates a normalcy function. In portion 6 of Fig. 1 and further described in the paragraph starting at column 16, line 9, Clarke discloses malignancy and benignancy functions for classifying a mass.

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Page 5

Application/Control Number: 09/943,347

Art Unit: 2621

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 13. Claims 5, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in view of Abdel-Motaleb (5,768,333).
- 14. In regards to claims 5, 8, and 11, Clarke as shown above, in response to claim 3, has everything in common with claims 5, 8, and 11 except for explicitly stating that Mahlanobis distance is used with the normalcy, benignancy, and malignancy functions.
- 15. Abdel-Motaleb teaches of a system for classifying abnormal shadows. Abdel-Motaleb discloses in the paragraph starting at column 8, line 60 using Mahalanobis distance to compute the benignancy and malignancy functions.
- 16. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use Mahalanobis distance (as taught by Abdel-Motaleb) when analyzing abnormal shadows. When dealing with a decision making system that outputs functions suggesting the likelihood of malignancy or benignancy the system needs the third options of normalcy. In order to provide consistant results all three functions should be based upon the same design, in this case Mahalanobis distance. Mahalanobis distance is a very effective way of finding the similarity between sets of

Application/Control Number: 09/943,347

Art Unit: 2621

values. The system disclosed by Clarke uses Neural Networks for classification, similarity is one of the foundations Neural Networks are based upon. Thus using Mahalanobis distance can provide more accurate results, preventing many unnecessary surgeries and catching cancer at its very earliest stages.

Allowable Subject Matter

17. Claims 4, 7, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

- 18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 19. US Pat. 5,832,103 is discloses a system for classifying masses in a mammogram.
- 20. US Pat. 5,984,870 is another patent on a system for classifying masses in mammograms, which goes into further detail on classification techniques.

US Pat. 6,272,233 discloses a system for classifying masses in mammograms which uses Mahalanobis distance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L Lavin whose telephone number is 703-306-4220. The examiner can normally be reached on M - F (8:30 - 5:00).

Application/Control Number: 09/943,347

Art Unit: 2621

Page 7

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Boudreau can be reached on (703)305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLL

LEO BOUDREAU SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 2600